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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,032	07/26/2001	Gregory M. Fahy	074066-0100	9126
30542	7590	01/24/2006	EXAMINER	
FOLEY & LARDNER LLP P.O. BOX 80278 SAN DIEGO, CA 92138-0278			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/916,032

Applicant(s)

FAHY, GREGORY M.

Examiner

Deborah K. Ware

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-32 and 34-45 is/are pending in the application.
- 4a) Of the above claim(s) 29, 30 and 38-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 31, 32 and 34-37 is/are rejected.
- 7) ☒ Claim(s) 20-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

Claims 19-32 and 34-45 are pending.

Claims 1-18 and 33 are canceled.

### ***Response to Amendment***

The amendment and arguments filed November 11, 2005, have been received entered. The change of customer number request is noted as well and has been changed to 30542.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

As noted in the last office action of May 12, 2005, this Application is a CIP of case Serial No. 09/771,221, filed January 26, 2001, which claims benefit of 60/178,157, filed January 26, 2000. The CIP has been abandoned. Applicant's response to update the status of the CIP case at page 1, line 6, of the instantly filed specification, is respectfully appreciated by the examiner.

Applicant's arguments have overcome the rejections set forth in the prior action with respect to the 35 USC 112 statute under first and second paragraphs, and those rejections have been removed.

### ***Election***

Applicant's election with traverse of Group I, claims 19-28 and 31-37, in the reply filed on September 25 2003 is acknowledged. The traversal is on the ground(s) that there is no undue burden to the examiner and that the same search for Group I can also be used for Group III.

This is not found persuasive because there are different method steps employed for Group III, that are not required of Group I. The methods of Group I, require the steps of preparing preservation medium, adding preservation medium, and cooling whereas, method of Group III requires preparing two protective solutions, a first protective solution and second protective solution, and then contacting each with the living system at two separate temperature ranges, a first temperature range and a second temperature range to effect the cooling steps.

Thus, two separate cooling steps are also required of Group III. Thus, the different process steps means a different search is required for Group III, which is not required of Group I, and this would present a burden on the examiner to search for these two separate and distinct inventions because there is two way distinctness between the two since no preparation of a preservation medium and adding of it to a living system are required. Further, two distinct and separate inventions are recognized to be classified in separate and distinct classes.

Claims 29-30 and 38-45 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 25, 2003.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 5122005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19, 31-32 and 34-36 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited Fahy et al. (US Patent No. 6,616,858) as cited on <sup>previously</sup> enclosed PTO-892 Form (A), for reasons of record.

Claims are drawn to methods for reducing or eliminating cooling injury in a living system comprising: preparing a preservation medium having a tonicity which is sufficiently hypertonic to minimize cooling injury, wherein the medium comprises a carrier solution and cryoprotective agent. The agent can be dimethyl sulfoxide (DMSO),

Art Unit: 1651

formamide, and ethylene glycol. Also it can comprise antinucleating polymers such as polyglycerol and polyvinyl alcohol-polyvinyl acetate copolymer in combination at a total concentration of 0.1 to 0.7 times isotonic. The polyethylene glycol can have a mean molecular mass of 1000 daltons. The carrier solution can also comprise polyvinyl pyrrolidone having a mean molecular mass of 5000 daltons. In addition the method includes adding the medium to the living system and cooling the living system to a temperature below 0 °C.

Fahy et al ('858) teach methods for reducing or eliminating cooling injury in a living system comprising: preparing a preservation medium to minimize cooling injury, wherein the medium comprises a carrier solution and cryoprotective agent. Note the abstract and Figures 3-4, column 1, lines 10-12 and column 5, lines 1-6. The agent can be dimethyl sulfoxide (DMSO) (see column 9, line 38), formamide (see column 9, line 39), and ethylene glycol (see column 11, line 57). Also it can comprise antinucleating polymers such as polyglycerol (see abstract and column 11, line 3) and polyvinyl alcohol-polyvinyl acetate copolymer (see the abstract) in combination at a total concentration of 0.1 to 0.7 times isotonic (see column 16, lines 66-67). The polyethylene glycol can have a mean molecular mass of 1000 daltons (see column 12, line 34). The carrier solution can also comprise polyvinyl pyrrolidone having a mean molecular mass of 5000 daltons (see column 14, lines 42-43). In addition the method includes adding the medium to the living system and cooling the living system to a temperature below 0 °C (see column 15, lines 27-28 and Figure 4).

The claims appear to be identical to the cited disclosure and are, therefore, considered to be anticipated by the teachings of the cited reference. The steps of preparing a preservation medium, adding it to a living system, and cooling a living system are disclosed; and its having a tonicity which is sufficiently hypertonic to minimize cooling injury is inherent to the medium of Fahy et al ('858). The identical ingredients are in the preservation medium disclosed by Fahy et al, and provide the same function which is minimal injury to a living system. The tonicity of Fahy et al ('858) is inherently sufficiently hypertonic to minimize cooling injury by the presence of these ingredients since Fahy et al disclose the identical preservation medium which includes these ingredients.

However, in the alternative that there is some unidentified claim characteristic for which provides for a difference between the claims and Fahy et al ('858), then such difference is considered to be so slight as to render the claims *prima facie* obvious over the cited reference.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a preservation medium having tonicity which is sufficiently hypertonic to minimize cooling injury via the preservation medium comprising the disclosed ingredients, adding it to a living system, and cooling the living system as disclosed by Fahy et al.

Clearly one of skill would have expected successful results for minimizing cooling injury as Fahy et al teach the same. The same ingredients to prepare the preservation medium are disclosed by Fahy et al and the same successful result of minimizing

Art Unit: 1651

cooling injury is achieved upon adding it to a living system, and then cooling the living system. The steps of preparing a preservation medium, and adding it to a living system and cooling the living system are clearly disclosed.

One of skill would have been motivated to select for these ingredients as disclosed by Fahy et al. The medium would have at least been expected to be successful and sufficiently hypertonic to minimize cooling injury. In the absence of persuasive evidence to the contrary the claims are alternatively rendered prima facie obvious.

### ***Response to Arguments***

Applicant's arguments filed November 11, 2005, have been fully considered but they are not persuasive. The argument that the prior art does not address reducing or eliminating cooling injury is not convincing because Applicants' own specification clearly disclose that ice formation causes injury during cooling, note the instant specification at page 1, lines 25-26. The cited reference US Pat No. '858 clearly teaches that prevention of ice formation has utility in any situation in which ice formation has adverse or undesired effects, and hence ice formation causes cooling injury. Therefore, the cited reference clearly teaches reducing or eliminating cooling injury in a living system. Applicants' claims are not limited to any particular type of cooling injury per se.

The argument that the applied prior art of record does not disclose the method as claimed herein is not persuasive because the cited reference US Pat No. '858 clearly teaches preserving a living system using a cryoprotectant and polymer in solution (i.e. polyglycerol, or PGL), note column 5, lines 40-44. Note that PGL is effective alone or in



Art Unit: 1651

combination with polyvinyl alcohol, or PVA. The preservation is taught to be performed at a state below 0 ° C, note column 5, lines 9-10. The solution can be a water solution which is a carrier solution.

Further, the argument that prevention of ice formation is different from prevention of cooling injury is not persuasive because Applicant's own specification, as noted above, teaches that such ice formation is an example of a cooling injury in a living system. Also the cited reference US Pat No. '858 clearly teaches the desire to minimize toxicity, note column 5, lines 1-5. Cooling injury is a broad term and not limited in the instant claims to Applicant's Figure 3 at [0069] or at [0070] of their specification, especially since as noted above, cooling injury is a result of ice formation as noted at page 1, lines 24-26 of Applicant's specification. Hence, the instant disclosure and Applicant's arguments are somewhat conflicted by the teaching that ice formation is a cooling injury.

Also cooling does occur below 0 ° C as claimed herein, and the cited reference teaches cooling below 0 ° C, note column 5, lines 9-10. Thus, the argument that the reference does not teach cooling or that ice formation disclosed in the reference is not from cooling is not deemed persuasive. Furthermore, Applicants' instant claims are not limited to the exemplified disclosure as argued by Applicant at page 22, of their fax response. The function disclosed by the cited reference is identical to the claimed method. The '858 patent does indeed describe or suggest prevention of cooling injury and the rejection, is therefore, deemed proper and maintained.

***Claim Rejections - 35 USC § 103***

Claim 37 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy et al ('858 as noted above) in view of newly cited Fahy et al (US Patent No. 6,395,467), as cited on enclosed PTO-892 Form (B).

Claim 37 is drawn to a croprotective agent which further comprises acetol.

Fahy et al ('858 noted above) is discussed above.

Fahy et al (US Patent No. 6,395,467) teach acetol at column 19, line 58.

The claim 37 differs from Fahy et al ('858) since acetol is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine with the preservation medium of Fahy et al ('858) with the acetol disclosed by Fahy et al ('467) to carry out the method for reducing cooling injury in a living system. Acetol is clearly disclosed at Table 4, column 19, line 58, and one of skill would have expected successful results of selecting for acetol based upon this teaching wherein it clearly forms a superior carrier solution. Therefore, one of skill would have been motivated to select for acetol. Thus, in the absence of persuasive evidence to the contrary the claim is rendered prima facie obvious over the cited prior art.

***Response to Arguments***

Applicant's arguments filed November 11, 2005, have been fully considered but they are not persuasive. The argument that cooling injury is not disclosed is adequately discussed above and incorporated herein since it is the same argument the examiner's rebuttal is the same. Furthermore, in response to applicant's arguments against the

Art Unit: 1651

references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In addition, the argument that there is not a reason to combine is not persuasive because the secondary reference '467 clearly teaches a solution containing the acetol and one of skill would have expected successful results for its application within a carrier solution as disclosed by the primary reference '858. Applicant has provided no reason that the acetol would not be successful in the carrier solution of the primary reference '858. Thus, the rejection is deemed proper and is maintained.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 20-28 are rendered free of the prior art, but are objected to for being dependent upon a rejected base claim(s).

Art Unit: 1651


Claims 19, 31-32 and 34-37 fail to be patentably distinguishable over the state of the art discussed above and cited of record. Therefore, the claims are properly rejected.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Deborah K. Ware  
January 19, 2006

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1265